Maryland Board of Pharmacy Public Meeting Minutes

Date: July 20, 2011

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner			1	0
Chason, D.	Commissioner			1	0
Finke, H.	Commissioner			1	0
Gavgani, M. Z.	Commissioner		X	0	1
Handelman, M.	Commissioner			1	0
Israbian-Jamgochian, L.	Commissioner/Treasurer			1	0
Matens, R.	Commissioner		X	0	1
Souranis, M.	Commissioner//President			1	0
St. Cyr, II, Z. W.	Commissioner			1	0
Taylor, D.	Commissioner			1	0
Taylor, R.	Commissioner/Secretary		X	0	1
Zimmer, R.	Commissioner			1	0
Bethman, L.	Board Counsel			1	0
Felter, B.	Assistant Board Counsel			1	0
Naesea, L.	Executive Director			1	0
Wu, Y.	Compliance Manager		X	0	1
Daniels, D	Licensing Manager			1	0
Gaither, P.	Administration and Public Support Manager			1	0
Jeffers, A.	Legislation/Regulations Manager			1	0

Subject	Responsible		Action Due Date	Board
	Party	Discussion	(Assigned To)	Action
I. Executive	M.	Members of the Board with a conflict of interest relating to any		
Committee	Souranis,	item on the agenda are advised to notify the Board at this time or		
Report(s)	Board	when the issue is addressed in the agenda.		
	President			
		1. Call to Order	1. N/A	1. Mike Souranis called the Public Meeting to order at <u>9:45</u> A.M.
		2. Sign-in Introduction and of meeting attendees – (Please indicate on sign-in sheet if you are requesting CE Units for attendance)	2. N/A	2. No action required.

Subject	Responsible		Action Due Date	Board
	Party	Discussion	(Assigned To)	Action
		 . Mike Souranis requested all meeting attendees to introduce themselves and to remember to sign the guests list before leaving the meeting. 3. Distribution of packet materials - M. Souranis reported that guests will be given packets of materials so that they can follow meeting discussions. He requested that all guests return the draft packets before leaving the meeting. 	3. Materials to be collect at conclusion of Public Meeting.	3. No action required.
	R. Taylor Secretary	4. Review & Approval of Minutes of June 15, 2011 Minutes were review and amended as follows: pg. 2 – Meeting Updates – L. Bradley-Baker also attended MPhA; pg. 9 – should say "custodial parents sign for minors." A. Jeffers noted that the wording in the proposed regulation was correct when it was sent for processing L. Bradley-Baker will submit minor grammatical changes.	4. Minutes to be amended as voted. (Board staff)	4. Motion: L. Israbian- Jamgochian moved to accept minutes as amended. Z. St.Cyr seconded. The motion was
		5. Omission of Voted Item in December 15, 2010 Minutes – Approval of Amendment Required The vote to increase per diem from \$150 to \$200, effective June 1, 2011 was omitted from the June 2011 accepted Minutes.	5. December 15, 2010 Minutes to be amended as approved. (Board staff)	carried. 5. Motion: Z. St. Cyr II moved to accept an amendment to include omitted language to the December 15 th 2010 Minutes.
				Seconded: H. Finke. The motion was carried
II. Staff Operations Report (s)	L. Naesea,	1. Operations Updates - L. Naesea reported that there was a recent security breach at the Board resulting in the termination of an employee; A second employee, MIS Manager T. Banks is no longer employed with the Board. L. Naesea acknowledged the long term relationships T. Banks had with licenses and other constituents and indicated that the Board would continue to meet their MIS needs. The SQL data base installation project is on-going and staff is working with DHMH to develop a short-term vendor contract for a project manager. A request will also be made to transfer budget funds to pay for the procurement. The Board's data base specialist and hardware vendor, M. Hsu and J.B. Bozek, will perform	1. Updates	1 No Board action required.

Subject	Responsible	Discussion	Action Due Date	Board
	Party	Discussion required daily MIS functions.	(Assigned To)	Action
		2. DHMH Preliminary Audit Report - The preliminary audit report indicated that the Board could not demonstrate that it accounted for pre-numbered licenses. A system has been put into effect to address this identified concern.	2. L. Naesea will prepare a response to the preliminary report.	2. No Board Action required.
		3. Meeting Updates - D. Taylor attended a Division of Infectious Disease Control meeting in Baltimore City To discuss the Baltimore City's Needle Exchange Program model. The Division wants to use the City's model in other jurisdictions throughout the State. There is a particular interested in pharmacists becoming more involved. D. Taylor mentioned that although pharmacy laws would not prevent this, there may be drug paraphernalia laws that could. He commented that it was positive that pharmacy was included as a part of this initiative. Senator P. Hollinger commented that she had sponsored Baltimore City's initial legislation for the Needle Exchange program, which has helped decrease the spread of HIV, in addition to supporting efforts to encourage addicts to enter into treatment. L. Naesea reminded members that Richard Matens would be attending subsequent meetings with D. Taylor because of his former involvement with and knowledge of the Baltimore City Health Department's exchange program.	3. Meeting Updates	3. No Board Action required.
		4. Correspondence a. MPhA Resolution - Executive Director, H. Schiff sent a letter to the Board to encouraged the Board it to reactivate the Acetaminophen Task Force in order to recommend that the sale of OTC immediate-acting acetaminophen containing more than 325 mg per unit dose be limited to 100 doses per container. M. Souranis noted that this may be more of an issue for the FDA since the data on the issue should be researched to determine the advantages and/or disadvantages of limiting the sales. D. Taylor suggested that the Board write a letter to since this is more of a manufacturing issue. H. Schiff indicated that the FDA has taken actions in the past based on the Acetaminophen Task Force recommendations. It was suggested that MPhA address the issue through its organization. L. Bradley-Baker indicated her	a. L. Bradley Baker will work with MPhA on next steps and report outcomes to the Board.	a. No Board vote required.

Subject	Responsible	Digorasias	Action Due Date	Board
	Party	Discussion willingness to reconvene the group on this issue, but would also be	(Assigned To)	Action
		willing to attend a meeting MPhA and bring necessary background		
		information from the deactivated task force deliberations.		
		information from the dedect valed task force deflectations.		
		b. C. Lawson sent an e-mail to the Board on behalf of the U of M	4b. The Board will post	4b. Motioned: L.
		School of Pharmacy to apprise of its current survey that requires	information about the	Bradley-Baker
		pharmacist immunizers' participation. She asked the Board to	pharmacist immunizer survey	Seconded: D. Taylor
		consider partnering on this project in order to increase distribution	on its web site and in	
		of the survey and gain greater participation. L. Bradley-Baker	newsletter after notification	The motion carried.
		indicated that the addition of the Board as a partner and its role	that the IRB change approval	
		would require IRB approval, but felt otherwise it would be a good	is received. (L. Naesea)	
		project in which the Board could become involved.		
		5. Sunset Review Board members will be interviewed	5. N/A	5. No Board Action
		individually.	0.1,71	required.
				•
B. Administration	P. Gaither,	Personnel Updates –	4 37/4	N D 14 4
and Public Support	Manager	1. Vacancies and Recruitments - Courtney Jackson has been	1. N/A	No Board Action
		appointed as a permanent employee assigned as secretary for the Compliance Unit. She has temporarily been assigned to support		required.
		the Licensing Unit until the Pharmacy Technician Specialist		
		vacancy is filled. The Board is awaiting approval for existing		
		freeze exemptions requests and anticipates approval in July.		
		needs enemptions requests and uniterpates approvides in vary.		
		2. Contracts and Procurement - The APS Unit has procured	2. N/A	
		contracts for expert witnesses for two separate disciplinary cases.		
		As previously noted contracts are also in development for project		
		management of the MIS database project and for NABP to act as		
		an agent for the Board with wholesale distributor inspections.		
		3. NABP District I & II meeting – The meeting is scheduled in	3. N/A	
		October to be held in Boston, MA. The E.D and Board delegate,	3.17/1	
		L. Israbian-Jamgochian will attend.		
C. MIS	L. Naesea	Department Initiative – SharePoint The DHMH SharePoint	N/A	No Board Action
		new web site project is ongoing. L Naesea will work with		required.
		Systems Automation to ensure that the Board's required		
		reconfigured screens will properly interface with the design for its		
D. Linnai	D. Daritala	SQL database project.		
D. Licensing	D. Daniels,	Licensing Unit Updates:	N/A	No Board Action
	Manager	Monthly Statistics – Statistics for the end of the month of June	11/73	140 Doard Action

Subject	Responsible		Action Due Date	Board
	Party	Discussion were provided. D. Daniels noted that there had been a correction	(Assigned To)	Action required.
		made to previously reported statistics.		required.
E. Compliance	Y. Wu, Manager	Inspection Program Report - Statistics for the end of the month of June were provided.	1. N/A	1. No Board Action required.
		2. PEAC Update- T. Tommasello of PEAC indicated that they are tracking 22 cases. 51 drug tests results were received in the month of June with 2 positives. He also raised concerns regarding communications between the Board and PEAC related to an anonymous client. L. Naesea explained that a signed consent to release information form needed to be provided to the Board before it would discuss the client with PEAC.	2. The issue is to be discussed further between PEAC and the Board's assigned liaisons. (H. Fink and D. Chason)	2. No Board Action required.
F. Legislation & Regulations	A. Jeffers	1. Status of Proposed Regulations		
		a. 10.34.03 Inpatient Institutional Pharmacy	a. The proposed effective date	a. D. Taylor moved
		Published June 3, 2011 with comment period through July 5,	for the regulations is October	that effective date
		2011. No comments received. Notice of Final Action submitted.	1, 2011 to allow changes to be made to the inspection form. (A. Jeffers/Compliance Unit)	should be October 1, 2011. Seconded: R. Zimmer
				The motion was carried.
		b. 10.34.14 Opening and Closing of Pharmacies	b. N/A	b. No Board Action
		Referred to July 27, 2011 Practice Committee	(A. Jeffers)	required.
		c.10.34.25 Delivery of Prescriptions		
		Proposal and documentation to be submitted. New NORD submitted July 7, 2011.	c. N/A (A. Jeffers)	c. No Board Action required.
		d. 10.34.28 Automated Medication Systems	1.374	
		Released for informal comment June 21, 2011 – July 21, 2011.	d. N/A (A. Jeffers)	d. No Board Action required.
		Informal comments to be discussed at July 27, 2011 Practice		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
		Committee Meeting.		

e. 10.34.32 Pharmacist Administration of Vaccinations	e. <i>N/A</i>	a No Board Astion
(to be promulgated in consultation with the Department pursuant	(A. Jeffers)	e. No Board Action required.
to SB 845)		-
Board approval requested for the Practice recommendation to revise the draft regulations with 3 requirements when administering to individuals 9 years and older: 1) Provide the patient with the VIS from; 2) Obtain a signed consent form; and 3) "The pharmacist should observe the patient for a period of time after administration of the vaccine." Submitted to the Department for review June 23, 2011. NORD submitted July 7, 2011.		
f. 10.34.32 Pharmacist Administration of Vaccinations – inclusion of travel vaccines – meeting scheduled with Bd. of Nursing and Bd. of Physicians for August 31, 2011.	f. N/A	f. No Board Action required.
g. 10.34.33 Prescription Drug Repository Programs - A Board Subcommittee is continuing to work on wording and waiting for the promulgation of the federal regulations this summer. Meeting scheduled with the Attorney General's Office for September 28, 201.	g. N/A	g. No Board Action required.
h. 10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment Anticipated to be published August 12, 2011 with comment period through September 12, 201.	h. N/A	h. No Board Action required.
i. 10.13.01 Dispensing of Prescription Drugs by a Licensee		
-A meeting was held with representatives from the stakeholder Boards per direction from Wendy Kronmiller on September 30, 2010. -DDC PIA request for Inspection Reports – DDC requested an extension until December 17 th - Received December 16, 2010. -Legislation was introduced, but did not pass. -The Senate Education, Health and Environmental Affairs Committee, Health -Subcommittee were expected to meet in June	i. N/A	i. No Board Action required.

the dispensing of prescription drugs by licensees.

-Sara Fidler, Counsel for EHE, indicated that Senator Joan Carter Conway wanted the Boards to meet with Sara Fidler and let her know what cannot be resolved.

j. 10.44.30 Board of Dental Examiners - Record Keeping

Comments due August 1, 2011. D. Taylor stated that the proposed regulations should require that a list of all of each patient's medications be included in each patient's record. R. Zimmer commented that the medications should be included in the clinical notes for each patient.

2. Proposed Legislation for the 2012 Legislative Session "Concept" legislative proposals submitted on July 15, 2011.

a. Health Occupations - Pharmacy - Dispensing Prescribers

<u>Proposal Form A 2012 - prescriber dispensing</u> Concept would require the Division of Drug Control to inspect applying dispensing prescribers sites before the dispensing permit is issued and then annually thereafter. All prescriptions medications dispensed to children should have child

instructions. Dispensing prescribers only be allowed to receive a permit to dispense if located 10 miles or more from the closest pharmacy. (This

caused a discussion about Patient First and similar places.) M. Souranis explained that there are more dispensing prescribers than licensed pharmacies in Maryland. From the Board's perspective, allowing them to practice under less restrictive regulations than trained pharmacists is does not promote patient safety. The Board has observed many errors and neglect on the part of dispensing prescribers to even follow current regulatory requirements.

b. Health Occupations – Board of Pharmacy – Jurisdiction of Non-resident Pharmacies

Form A 2012 Non-resident complying w MD Law

j. Provide comments to the Dental Board requesting that proposed regulations should require that a list of all of each patients' medications be included in each patient's record and included as part of the clinical notes.

2. Board ratification requested for 3 draft bills and/or concept proposals.

2. The three legislative concept papers/draft bills submitted to OGA were ratified by the Board.

j. D. Taylor moved to

comments to the Board

send a letter with

Board of Pharmacy

of Dental Examiners

Seconded: H. Finke

The motion carried.

		Concept is to require out-of-state pharmacists who work in out-of-state MD permitted pharmacies to be licensed. L. Bethman clarified that this proposal would allow the Board to have direct jurisdiction over out-of-state pharmacists thereby better protecting MD patient who are dispense medications from out of state pharmacists. c. Health Occupations – Wholesale Distributors - Criminal Background Checks and Inspections Form A 2012. Wholesale Drug Distributors Concept would be to require all designed representatives and supervisors to submit their background information directly to CJIS rather than through the Board. The proposed legislation would also alter regulatory requirements for wholesale distributors that do not hold product. Rather than being required to be physically inspected they would need to submit certain paperwork to the Board for review and approval prior to being approved for a permit. L. Naesea indicated that if approved, it would eliminate the need for the Board to contract for these types of wholesale distributors who are out of state to be inspected by a Board contracted agent.		
III. Committee Reports A. Practice Committee	H. Finke, Chair,	Letters for Board Approval 1. Stephanie M. Hammonds, Pharm D., LifeBridge Health — requested Computer terminal to double as dispensing terminal and cash register. Draft Bd. Response — 2. Dr. Geoffrey Buff Suboxone for pain Draft Board Response - Suboxone for pain-revised response indicated that that it is legal to dispense Buprenorphine or Suboxone as long as provider is substance abuse management	1. Letter was amended to require that the computer terminal be located in a licensed pharmacy and a licensed pharmacist must be present when dispensing medications. (A. Jeffers) 2. N/A (A. Jeffers)	1. Practice Committee recommended approval of letter as amended. Seconded: Israbian-Jamgochian. The motion carried. 2. Practice Committee move for approval of the letter as had been revised. Seconded: L. Israbian-Jamgochian The motion carried.

		certified. L. Bethman advised that SAMSHA does not require physician waiver certification if the medication is only being used for pain management .		
B. Licensing Committee	D. Chason, Chair	1. Pszczola, Shelley - Applicant did not provide documentation of having met live CE requirements which were obtained after deadline. Was told to submit late fee but did not send, has asked for reinstatement without fee.	1. After discussing the application and the required CE requirements (Medication Errors credits did not appear to have been taken) it was suggested that the case be sent back to the Licensing Committee for further consideration.	1. The Licensing Committee moved to refer the application back to the Licensing Committee for further review. Seconded: R. Zimmer The motion carried.
		2. ElRey Rx Inc. - Change of ownership for California compounding pharmacy.	2. Withdrawn from consideration on the agenda	2. No Board Action required.
		3. Clayton Pharmacy – Prescription Repository Application (late addition to the agenda)	3. Committee recommended application approval.	3. The Licensing Committee moved for approval of the Clayton Pharmacy to become a Prescription Drug Repository Seconded: H. Finke The motion was carried.
C. Public Relations Committee	L. Bradley- Baker Chair	1. Newsletter – The 2011 Summer edition has been mailed. The timeline for the Fall edition is being circulated.	1. N/A	1. No Board Action required.
		2. Annual Report – The reports were disseminated at the MPhA annual meeting in Ocean City. All Board members, staff, constituents and State Legislative office received copies as required.	2. N/A	2. No Board Action required.
		3. Annual CE Training – The Board sponsored annual training is planned on October 2, 2011 at the Maritime Institute. The program, entitled, <i>Emergency Preparedness: Pharmacists' Role Before, During and After Disasters</i> Will feature presenter Dr. Yeskey, Director of Quality Affairs in the Office of the Assistant Secretary for the Office of Preparedness and Response at the Department of Health and Human Services who will discuss the pharmacist's roles during an emergency event on the federal level.	3. The PR Committee recommended approval of the proposed program.	3. The Committee moved for approval of the recommendation. Seconded: R. Zimmer The motion carried.

		A panel discussion led by the EP Task Force members will discuss the State's plan for disasters. 4. National Consumer League Campaign – The PR Committee recommends that the Board partner with this campaign that is targeting six U.S. Cities. It is entitled <i>Scripting the Future</i> " is intended to educate the Public on the importance of know their prescribed medications, taking them appropriately and understanding why they are taking them. It will include distribution of literature and flyers, marketing commercials, on-line postings, and other similar approaches. L. Bradley Baker has been involved through her affiliation with ACPE and had suggested the Board's involvement prior to the Board's receipt of an invitation from DHMH Deputy Secretary of Public Health, Francis Phillips for the Board to support the campaign. The campaign will be launched in the Baltimore area in September or October 2011.	4. The PR Committee recommended formally submitting a form to commit the Board's involvement and participation in planning.	4. The Committee moved for approval of its recommendation To become a participant in the campaign. Seconded: Z. St. Cyr The motion carried.
D. Disciplinary	L. Israbian- Jamgochian Chair	Committee Updates – 43 complaints were received by the Board in the month of June. A total of 24 formal actions have been taken by the Board. The next Disciplinary meeting is schedule on July 29, 2011.	N/A	No Board Action required.
E. Emergency Preparedness Task Force	D. Taylor Chair	 Task Force Updates: 1. Safety Vests - Vests for to be worn by volunteers at State emergency sites were ordered and have arrived. The vests will allow for easy identification of pharmacist volunteers. 	a. N/A	1. No Board Action required.
		2. 2 nd RSS Site - The Department has applied to CDC for approval of a 2 nd RSS site. Construction of the site is complete and CDC has to inspect before approving.	b. N/A	2. No Board Action required.
F. Drug Therapy Management	Rodney Taylor Co-Board Representati ve	1. Template Protocol Language Disallowing substitution of Chemically Dissimilar Drugs in Pharmacist/Physician/Patient Contracts - Board representatives met with the DTM Joint Committee on July 13, 2011. The protocol approvals have taken extended periods of time for review and approval. Four applications with associated protocols will be submitted to the Board of Physicians boards for approval if they agree to delete any language they references that the substitution of chemically dissimilar drugs may be allowed in the patient/pharmacist/physician contracts. The Board of Physicians wants the Committee to develop a template for language disallowing the substitution of chemically dissimilar prescriptions in the contracts	1. It was recommended that a letter be sent to Secretary Sharfstein to apprise him of the proposed used of templates that would disallow the substitution of chemically dissimilar drugs in physician/pharmacist/ patient contract, despite the fact that regulations allow this to occur.	1. H. Finke moved that the recommendation be accepted. Seconded: L. Israbian-Jamgochian. The motion carried.

 indicating that they will not recommend approval of any protocols that does not apply the template language. The templates were presented for consideration by the Board's DTM Joint Committee Representatives.

The application templates are needed to clarify information required. They were created by Robin Bailey, the Board of Physicians new Health Policy Analyst. If approved, they would replace some to the current templates associated with the DTM application on the Board's web site. L. Israbian-Jamgochian questioned whether the "chemically dissimilar" language that the Board of Pharmacy disagrees with. She stated that communication between the pharmacist and physician on substitution of certain drugs that yield the same effect, particularly if a patient has an immediate need and it is allowed in the pharmacist/physician/patient contract. L. Bethman reminded members that the Board of Physicians may deny an entire protocol and L. Naesea added that a denial by one Board means the DTM protocol is denied in totality. If the wording is not changed, all of the applications will continue to be denied. Some members felt that the templates should move forward and allow individual applicant to elect whether to challenge to the changes required for approval.

M. Souranis noted that already approve protocols are due for renewal and questioned whether they would be forced to end their projects if they refused to use the new template language. L. Naesea recommended that the Board request Secretary Sharfstein to review the matter before determining whether to allow the use of the templates in the application; otherwise potential applicants would be discouraged from submitting protocols.

2. Drug Therapy Management Protocols Considered for Approval— The protocols currently under consideration are:

a. Peoples Community Health – <u>Anxiety, Mood Disorders, Schizophrenia, and Buphrenorphine</u> (all approved by Board of Pharmacy in December with "chemically dissimilar language included. Peoples Community Health submitted two versions of each protocol – one with the proposed template language in and the other with the language removed. . The Board of Pharmacy sent a letter to Peoples Community Health on behalf of the Committee. The letter also indicated that Board of Physicians also

a. N/A

a. No Board Action required.

		wants this applicant to submit evidence of that all waiver certifications for the Buprenorphine protocol have been acquired for the involved practitioners. Peoples sent the waiver certifications for the involved physicians and indicated in their response that Peoples has decided to stick with their first submission that contains the language that allows "chemically dissimilar substitution" if it is noted in the individual in the contracts		
		b. Univ. of MD College Park – Asthma, Allergic Rhinitis, Tobacco Use and Dependence – (previously approved by the Board of Pharmacy in December 2010). The Board of Physician DTM committee members will recommend approval to their full Board if the recommended template language is used.	b. N/A	b. No Board Action required.
		c. Fink's Pharmacy – <u>Metabolic Syndrome</u> (renewal application with changes) – The Board of Physicians did not approve this protocol because it did not agree with the applicants plan to allow protocol physicians to not be located at the site from the pharmacy. The Board of Physicians has invited the applicant to come to their August 25, 2011 meeting to explain their application plans.	c. Committee recommended approval of Fink's Pharmacy renewal of the Metabolic Syndrome protocol as amended.	c. No vote was taken.
		2. Protocols on August Agenda - Sinai Hospital – Thrombosis application and Protocol was approved by the Board of Physicians and Board of Pharmacy. Union Memorial Hospital – Anticoagulation Services and PharmaCare Network – Coumadin Monitoring will be discussed at the next DTM Joint Committee meeting in August.		
		4. Staffing Assignment - L. Naesea announced that she has temporarily assigned A. Jeffers to staff the DTM Joint Committee on behalf of the Board of Pharmacy. She will assume full responsibility for that new role between September and December 2011.		
IV. Other Business & FYI	M. Souranis R. Matens	FYI Board Retreat Update – there has been one planning meeting and a second is scheduled on August 16, 2011. R. Matens will provide details of the recent survey completed by Board and staff members	N/A	No Board Action required.

		a t the August Public Board meeting.	
V. Adjournment	M. Souranis, Board President	The Public Meeting was adjourned at 12:15 PM. B. At 12:20 P.M. Mike Souranis convened a Closed Public Session to conduct a medical review of technician applications.	
		C. The Closed Public Session was adjourned at 1:15 P.M. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	